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510(k) Summary

V.A.C.® GranuFoam™ Silver Dressing

1.	**Name/Address of Submitter:**	**Kinetic Concepts, Inc.** **8023 Vantage Drive** **San Antonio, TX 78265-9508**
2.	**Contact Person:**	**Judith Harbour, Manager Regulatory Affairs**
3.	**Date Summary Prepared:**	**June 16, 2004**
4.	**Name of Device:**	**V.A.C.® GranuFoam™ Silver Dressing**
5.	**Classification Name:**	**Accessory to Powered Suction Pump** **21 CFR 878.4780** **Class II**
6.	**Predicate Devices:**	**V.A.C.® GranuFoam™ dressing (K032310)** **Acticoat 7 Day Antimicrobial Dressing (K001519)**

7. Description of Device

The V.A.C.® GranuFoam™ Silver dressing is a modification to the V.A.C. product line of black, reticulated, polyurethane foam dressings, designed specifically for use with the V.A.C. family of feedback-controlled devices, including the miniV.A.C.®, V.A.C.® Freedom™ and V.A.C.® ATS™ systems, all currently marketed by KCI under 510(k) K032310. The modification is the addition of a silver containing coating to the GranuFoam™ dressing to allow for a silver option to the dressing line.

8. Indication For Use

The V.A.C.® GranuFoam™ Silver dressing is indicated as an effective barrier to bacterial penetration for patients who would benefit from the V.A.C.® Family of negative pressure devices to help promote wound healing. The barrier functions of the dressing may help reduce infection in chronic, acute, traumatic, subacute and dehisced wounds, diabetic ulcers, pressure ulcers, flaps, grafts and partial thickness burns.

9. Technological Characteristics and Substantial Equivalence

The substantial equivalence for the V.A.C®. GranuFoam™ Silver dressing is based on the indications, intended use and technological features. It is also substantially equivalent to Smith and Nephew's Acticoat 7 Antimicrobial dressing (K001519) and several other silver dressings currently on the market, in terms of an antimicrobial

barrier. Comparative bench testing was conducted on V.A.C. GranuFoam Silver dressing and Acticoat 7 Antimicrobial dressing.

The gamma-irradiated V.A.C. GranuFoam Silver Dressing was tested under GLP studies in accordance with ISO-10993 for a surface device in contact with breached or compromised surface with prolonged duration. The dressing was shown to be non-toxic, non-irritating and non-sensitizing.

Antimicrobial effectiveness of the silver in the dressing was addressed in separate in-vitro laboratory evaluations using licensed commercial reference laboratories.

10. Conclusion

Based on the information presented above it is concluded that the V.A.C.® GranuFoam™ Silver dressing can be marketed for its intended use and is substantially equivalent to the identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 7 2009

KCI USA, Inc.
% Ms. Christy Oviatt
6203 Farinon Drive
San Antonio, Texas 78230

Re: K041642
Trade/Device Name: V.A.C.® GranuFoam® Silver Protection Dressing
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: II
Product Code: OMP
Dated: December 30, 2004
Received: January 3, 2005

Dear Ms. Oviatt:

This letter corrects our substantially equivalent letter of January 25, 2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not

limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041642

Device Name: V.A.C. GranuFoam Silver Dressing

Indications For Use: The V.A.C. GranuFoam Silver Dressing is indicated as an effective barrier to bacterial penetration for patients who would benefit from the V.A.C. family of negative pressure devices to help promote wound healing. The barrier functions of the dressing may help reduce infection in chronic, acute, traumatic, subacute and dehisced wounds, diabetic ulcers, pressure ulcers, flaps, grafts, and partial burns.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041642